



Office of Centers,  
Training, and  
Resources

Cancer Centers Branch

6116 Executive Boulevard  
Suite 700, MSC 8345  
Bethesda, Maryland 20892-8345  
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<http://www.nci.nih.gov/cancercenters/>

U.S. Department of Health  
and Human Services  
National Institutes of Health

September 19, 2002

Dear Dr.:

You are invited to submit a research planning and development grant application (P20) directed at the aging/cancer research interface. The purpose of this solicitation is to expand the capacity of the NCI-designated Cancer Centers to engage in research that concentrates on aging- and age-related aspects of human cancer in persons aged 65 years and older. This is the age group at highest risk for cancer as well as that in which the major tumors primarily occur. The goal is to establish formal interdisciplinary research "Programs" to integrate aging and cancer research in NCI-designated Cancer Centers. Successful applicants to this initiative are expected to design and coordinate a research effort in a five-year project period that will result in a formal aging/cancer "Program" or an equivalently effective integrated research activity that becomes a component of the NCI-funded Cancer Center Support Grant (CCSG).

The foundation for this research solicitation was created in the workshop, Exploring the Role of Cancer Centers for Integrating Aging and Cancer Research, June 13-15, 2001. This meeting, organized by the National Institute on Aging (NIA) and the NCI, provided a forum for senior leaders in cancer and aging research across a broad scientific spectrum to express their views on pressing research needs. A copy of the workshop report is appended. All cancer center applicants are required to make specific use of the Workshop Report in preparing a grant application. The report is also available on the website: <http://nia.nih.gov/health/nianci>

The attachment, Request for Applications for Integrating Aging and Cancer Research, provides full details regarding the background and guidelines for development of the P20 application. Applicants may apply for up to \$500,000 in direct costs (estimated \$750,000 total costs per year) for up to five years. Applications are due January 14, 2003. Approximately five to seven P20 awards are anticipated. A letter of intent, to be submitted by December 17, 2002, is requested.

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If you have questions regarding this initiative, please contact Dr. Pat McCormick (301) 496-8531, [pm60y@nih.gov](mailto:pm60y@nih.gov) or Dr. Rosemary Yancik (301) 496-5278, [yancikr@nia.nih.gov](mailto:yancikr@nia.nih.gov). We look forward to seeing your application.

Sincerely,

*/signed/*  
Linda K. Weiss, Ph.D.  
Chief  
Cancer Centers Branch  
Office of Centers, Training, and Resources  
National Cancer Institute

*/signed/*  
Rosemary Yancik, Ph.D.  
Program Director  
Geriatrics Branch  
Geriatrics and Clinical Gerontology  
National Institute on Aging

Attachments (2)

## **Request for Applications (RFA CA-03-504) for Planning and Development (P20) Grants Integrating Aging and Cancer Research in NCI-Designated Cancer Centers**

**National Cancer Institute  
National Institute on Aging**

**Letter of Intent Receipt Date: December 17, 2002**  
**Application Receipt Date: January 14, 2003**

The National Cancer Institute (NCI) Office of Centers, Training, and Resources, Cancer Centers Branch and the National Institute on Aging (NIA) Geriatrics Clinical Oncology Program, Geriatrics Branch announce the availability of planning and development grants to develop and establish formal programs directed at the aging/cancer research interface within the NCI-designated Cancer Centers. The goal of this research solicitation is to expand the capacity of Cancer Centers to engage in pioneering research that concentrates on aging- and age-related aspects of human cancer. Successful applicants to this initiative are expected to design and coordinate a research effort in a five-year project period that will result in a formal aging/cancer "Program" or an equivalently effective integrated research activity that becomes a component of the NCI-funded Cancer Center Support Grant (CCSG). A solid, focused infrastructure for the conduct and continued development of an aging/cancer research program, allowing for incorporation of multiple disciplines and creative exploration of new approaches to cancer, should be established.

There is a clear need to encourage research which draws from expertise in many disciplines to focus on the problems of cancer in older persons. This initiative is an effort to mobilize expertise through a planning and implementation effort that accelerates research at the aging/cancer interface. The research initiative provides the initial resources to develop and create an integrated, interactive research capability with a significant base of externally funded, peer reviewed research projects in NCI-designated Cancer Centers that focuses on problems of cancer in the elderly. The disproportionate burden of cancer in the elderly is poorly understood and needs attention from the basic, clinical, and behavioral research communities that can bridge and integrate diverse scientific areas of aging and cancer research. The unique cancer center infrastructure and its critical mass of multidisciplinary expertise provide an ideal research setting for meeting the challenges inherent in integrating aging and cancer research. Cancer Centers have well-established interactive research environments, and they have the leadership, space, equipment, structure and resources available to take advantage of new research directions as opportunities arise.

Research projects must have a clear relevance to human cancer and aging. The research guidance for this solicitation comes from the NIA/NCI co-sponsored workshop, "Exploring the Role of Cancer Centers for Integrating Aging and Cancer Research," held on June 13-15, 2001. Insights and research recommendations from the plenary sessions and seven working groups of this workshop should be used as the foundation and basis for all proposed planning grant applications (See the SPECIAL REQUIREMENTS section below). Applicants to this research initiative are advised to obtain the final report of the NIA/NCI workshop (hereafter referenced as the Workshop Report) for the background information on the magnitude of the cancer problem for persons in the age segment of the U.S. population 65 years and older, for the seven thematic areas of research that can be included in these planning grants,

and for the research priorities within each thematic area that must be addressed by any research projects developed during this planning effort. The Workshop Report can be obtained at the following website: <http://nia.nih.gov/health/nianci>.

FY 2003 funds will provide NCI and NIA co-funded support for this collaborative cancer center research program initiative. Applicants may apply for up to \$500,000 in direct costs (estimated \$750,000 total costs per year) for up to five years. Approximately five to seven P20s are expected to be competitive based on the known scientific composition of institutions that currently are NCI-designated Cancer Centers. The P20 grants are expected to generate a competitive research base for a formal Cancer Center "Program" as defined by the Guidelines for Cancer Center Support Grant (CCSG) applications (available at <http://cancer.gov/cancercenters>) that integrates aging and cancer research and becomes a stable component of the CCSG.

The application receipt date for this solicitation is January 14, 2003. It is recommended that a letter of intent be submitted indicating the title of the project, name of the principal investigator, all other key personnel, collaborating institutions, and estimated costs. This should be submitted by December 17, 2002 to Dr. Patricia McCormick at the following address:

Cancer Centers Branch  
6116 Executive Boulevard  
Suite 700, MSC 8345  
Bethesda, MD 20892-8345

For express mail use: Rockville, MD 20852

Please see Attachment for detailed Application Instructions.

## RESEARCH OBJECTIVES

### Background

Among Americans of all ages, persons 65 years and older are at highest risk for cancer. Data from the National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) Program (1995-1999) show that close to 60% of all newly diagnosed cases occur in this age segment of the U.S. population. The incidence rate for persons 65 years and older is 2208.1 as compared to 229.2 per 100,000 population for persons under 65 years. The median age range for most major cancer deaths is between 70 and 74 years. A sixteen-fold difference in age-adjusted mortality rates (1140.1 per 100,000 population) is observed for persons age 65 years and older, as compared to the rate for persons under age 65 years (70.8 per 100,000 population).

Cancer statistics showing the disproportionately high burden of cancer for older Americans take on even greater significance when cast against the changing demographics of the aging population in the United States. The number of older persons diagnosed with cancer is expected to increase because of the overall

aging of the U.S. population and an unprecedented expansion of the age group 65 years and older in the next three decades. Changing mortality patterns, decreased fertility, and the aging of the "Baby Boom" cohort born between 1946 and 1964 (75 million persons) will have far-reaching effects on the future overall health status and cancer burden of Americans. This phenomenon must be factored into cancer research efforts. By 2030, 20% of the U.S. population will be 65 years and older. As the total population continues to age and increase in number, so will the aging of the older segment of the population. This will be reflected in age shifts within the 65+ segment of the U.S. population that will increase the proportion of persons 85 years and older from the current 4.3 million to nearly 9 million.

### Research Scope

A broad range of research along the cancer control spectrum and the biology intersect of aging and cancer is included under this scientific initiative. The research scope is based on the seven thematic areas defined in the NIA/NCI Workshop Report. Each thematic area in the Workshop Report introduces the research area(s), suggests key research questions, describes the cancer center role and its potential and presents the research priorities developed in the working group. This information should form the basis of all research conducted as part of any planning grant application. While applicants may pursue any of these areas, the application must include one or more of the three highlighted areas - **Group 2. Treatment Efficacy and Tolerance; Group 3. Effects of Comorbidity; and Group 7. The Biology of Aging and Cancer** - as a major emphasis. The seven thematic areas of research are:

1. Patterns of Care [studies with a focus on older patients using both prospective and retrospective data that could include community-based studies, patient management, cancer site-specific studies, and maximizing existing data (e.g., SEER special studies, HCFA linkage, tissue banks, family network studies)]
2. Treatment Efficacy and Tolerance [clinical trials, pharmacology of anticancer drugs, radiation therapy, surgery, available technology, other modalities, characterization of inadmissible older patients to clinical trials]
3. Effects of Comorbidity [studies could include problems of diagnosis and treatment, disability, functional limitations, assessment, recurrence, detection of second primaries]
4. Prevention, Risk Assessment and Screening [impediments for older-aged persons asymptomatic or with symptoms precluding their entrance to the preventive and health care system (e.g., delay behavior, insufficient knowledge of cancer risk), changes that occur in cancer risk as a function of aging]
5. Psychosocial Issues and Medical Effects [quality of life, quality of cancer survival, family and caregiver resources, early and late effects of treatment, quality cancer care, tumor recurrence, multiple primary tumors]
6. Palliative Care, End-of-Life Care, Pain Relief [studies focused on patients with advanced cancer]

and associated issues in palliative care including caregiver and family support]

7. The Biology of Aging and Cancer [genetics, molecular signatures, bench to bedside application, translational research, age-related changes as they contribute to mortality, a focus on older persons who are vulnerable to cancer as contrasted with those who are not (e.g., sibship studies)]

## MECHANISM OF SUPPORT

The RFA will use the NIH P20 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. Applicants may apply for up to 5 years of support.

**ALLOWABLE COSTS** - The general areas in which costs are allowable are as follows:

1. Salary for the principal investigator and co-principal investigator
2. Administrative costs essential to the planning effort
3. Costs for meetings, retreats, workshops, etc. to facilitate interactions and priority setting
4. Costs for the development and establishment of specialized resources that cannot be accommodated by existing CCSG shared resources
5. Costs for recruiting investigators critical for integrating aging and cancer research
6. Costs for pilot research projects for the purpose of generating preliminary data critical for the submission of competitive grant proposals to the NIH or other funding agencies that employ an NIH-modeled peer review process. In general, individual pilot projects should not exceed \$100,000 in direct costs per year and should be limited to approximately 2 years of support.

## FUNDS AVAILABLE

The estimated funds (total costs) available for the first-year of support for the entire program is \$5.0 million and the NIA/NCI expects to fund between 5 to 7 new awards.

Individual applicants may apply for up to \$500,000 in direct costs per year for five years.

In future years, as a formal cancer center "Program" is integrated into the CCSG, the budget of the P20 grant will not be reduced; rebudgeting will be allowed to continue sustaining and stabilizing this effort within the ALLOWABLE COSTS noted above. This is a one-time solicitation; there are no provisions to provide the option of competing continuation awards in the future. All new awards will be contingent upon the availability of funds and receipt of a sufficient number of applications of outstanding scientific and technical merit.

## ELIGIBLE INSTITUTIONS

Only NCI-designated Cancer Centers [i.e., institutions currently awarded a Cancer Center Support Grant

or CCSG] are eligible for this solicitation to plan for and establish a formal "Program" that addresses research at the interface of cancer and aging. There can be only ONE application per cancer center institution(s). Centers with established CCSG research programs in cancer/aging are not eligible to apply.

A research "Program" as defined by the CCSG Guidelines (see <http://cancer.gov/cancercenters> ) consists of an interactive, collaborative group of funded investigators who share common scientific interests and goals and a leader who provides intellectual stimulation and guidance to the program, giving it cohesion, focus, and direction. By the end of the 5-year funding period, Cancer Center planning grant recipients are expected to have a formal aging/cancer research "Program" (or an equivalently effective model) in place that sustains continuing interactions between cancer and aging researchers and has a stable base of competitive, peer-reviewed funded research at the interface of cancer and aging.

## INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

The Principal Investigator must be a successful senior investigator who can provide scientific and administrative leadership to this planning and development effort. Ideally, the Principal Investigator should have a background that bridges cancer and aging research OR there should be co-Principal Investigators who are both senior investigators and who represent cancer research and aging research, respectively. This individual or individuals should be fully qualified to assume leadership of the cancer center "Program" resulting from this planning and development grant. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

## SPECIAL REQUIREMENTS:

1. All applicants are required to make specific use of the Workshop Report, "Exploring the Role of Cancer Centers for Integrating Aging and Cancer Research," when preparing their grant application. This report is available on the following website: <http://nia.nih.gov/health/nianci>

The Workshop Report should be used in two ways:

- a. It should be used when deciding which one or more of the seven thematic areas (listed on page 3 under "Research Scope") will be emphasized in the development of a cancer center "Program" or an equivalently effective model. The Report also should be used to ensure that research developed within a thematic area addresses at least one or more of the research priorities identified by the workshop participants.
2. While all applicants may pursue any of the seven thematic areas in the Workshop Report, the application must include one or more of the following three thematic areas as a major emphasis:
  - a. Treatment Efficacy and Tolerance
  - b. Effects of Comorbidity
  - c. The Biology of Aging and Cancer

3. Each pilot project that is funded must be led by an investigator whose research background clearly bridges aging and cancer research OR by co-investigators, one who has a track record in cancer research and another with a track record in aging research.
4. All applicants are required to have their progress evaluated annually by the Cancer Center's external advisory group in the form of a written report which must be included as part of all non-competing renewal applications. The applicant is responsible for either following the recommendations of the external advisors OR providing a rationale within the non-competing renewal application for not following the recommendations.
5. All applicants must agree to participate in workshops organized by the NCI and the NIA for the purpose of sharing information and progress. These workshops may be organized yearly or every two years.
6. All applicants must agree to NCI/NIA staff visits as a means of discussing progress and identifying needs to improve the outcome of this planning effort.

#### WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Patricia McCormick, Ph.D.  
Program Director  
Cancer Centers Branch  
National Cancer Institute  
Telephone: (301) 496-8531  
FAX: (301) 402-0181  
Email: pm60y@nih.gov

Rosemary Yancik, Ph.D.  
Program Director  
Geriatrics Branch, Geriatrics and Clinical Gerontology Program  
National Institute on Aging  
Telephone: (301) 496-5278  
FAX: (301) 402-1784  
Email: yancikr@nia.nih.gov



Direct your questions about peer review issues to:

Referral Officer  
National Cancer Institute  
Division of Extramural Activities  
6116 Executive Boulevard, Room 8041, MSC 8329  
Bethesda, MD 20892-8329  
Telephone: (301) 496-3428  
FAX: (301) 402-0275  
Email: ncidearefof@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Ms. Eileen Natoli  
Section Chief  
Grants Administration Branch  
National Cancer Institute  
6120 Executive Blvd, EPS-243  
Bethesda, MD 20892  
Telephone: (301) 496-8791  
FAX: (301) 496-8601  
Email: natolie@gab.nci.nih.gov

## LETTER OF INTENT

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

It is highly recommended that prospective applicants submit a letter of intent that includes:

- o Descriptive title of the proposed research
- o Name, address, and telephone number of the Principal Investigator
- o Names, addresses and telephone numbers of other key personnel
- o Participating institution(s)
- o Reference the number and title of this RFA
- o Thematic area(s) anticipated to be developed

The letter of intent is due by December 17, 2002. The letter of intent should be sent to:

Patricia McCormick, Ph.D.  
Program Director

Cancer Centers Branch  
National Cancer Institute  
6116 Executive Boulevard  
Suite 700, MSC 8345  
Bethesda, MD 20892-8345  
Telephone: (301) 496-8531  
FAX: (301) 402-0181  
Email: pm60y@nih.gov

For Express Mail use: Rockville, MD 20852

**PREAPPLICATION CONSULTATION:** It is highly recommended that prospective applicants take advantage of a preapplication consultation with NCI and NIA staff. Videoconference, telephone conference, or face-to-face meetings can be arranged at the applicant's request.

#### **SUBMITTING AN APPLICATION:**

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact Grants Info, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov). Because of the special nature of this initiative, it does not follow the traditional format for a research grant application, so please follow the SUPPLEMENTAL INSTRUCTIONS below exactly as outlined when preparing your application.

#### **SUPPLEMENTAL INSTRUCTIONS:**

1. **Face Page:** Use Form Page 1 as instructed in the Form PHS 398 (rev. 5/01). On line 1 provide the title of your planning activity. For Line 2 enter the title "Integrating Aging and Cancer Research in NCI Cancer Centers" and the number of this RFA, which is CA-03-504. Remember to affix the RFA label that comes with the Form PHS 398 to the bottom of the Face Page.
2. **Description, Performance Sites, and Key Personnel:** In general follow the Form PHS 398 instructions for Form Page 2. Provide a descriptive abstract of the application. If there is not a senior scientist with expertise in both aging and cancer research, then it is highly recommended that this planning activity include both a principal investigator and a co-principal investigator, who should be senior scientists in your institution, one representing cancer research and the other representing aging research. Ideally, this planning activity will result in a cancer center "Program" mutually guided by a scientist in cancer research and a scientist in aging research. Thus, the P.I. and the Co-P.I. should be selected on the basis that they would become the Program Leader and the co-Program Leader of a formal "Program" in the cancer center.

3. Table of Contents: NOTE: the Table of Contents and Research Plan of the Form PHS 398 (rev. 5/01) application are not specifically tailored to the unique objectives of this initiative for "Integrating Aging and Cancer Research in NCI Cancer Centers." Therefore, organize the Table of Contents exactly as described below:

Face Page (use Form Page 1)

Description, Performance Sites and Key Personnel (use Form Page 2)

Table of Contents (as modified specifically for this initiative)

Biographical Sketches (use Biographical Sketch Form Page)

Detailed Budget for Initial Budget Period (use Form Page 4) - NOTE: this is not a modular grant application. Detailed budgets with justifications are expected.

- a. Total budget for initial budget period (this should be the sum of the budgets in b, c and d below)
- b. Initial budget for Administrative Component
- c. Initial budget for Planning and Evaluation Component
- d. Initial Budget for Developmental Component

Budget for Entire Proposed Period of Support (use Form Page 5)

- a. Total budget for entire proposed period of support (this should be the sum of the budgets in b, c and d below)
- b. Total budget for Administrative Component
- c. Total budget for Planning and Evaluation Component
- d. Total budget for Developmental Component

Budgets Pertaining to Consortium/Contractual Arrangements (if any)

Letters of Commitment

Implementation Plan (Replaces Research Plan in PHS 398 application)

- a. Background of aging and cancer research in the Institution
- b. Potential research opportunities within your Institution(s)
- c. Specific thematic area(s) proposed for development
- d. Chronological review of proposed planning and priority-setting activities
- e. Plans for conducting meetings, workshops and retreats
- f. Plans for developing pilot research projects in the proposed thematic area(s)
- g. Plans for enhancing currently existing CCSG resources and/or for developing specialized resources (if any) in support of aging and cancer research
- h. Plans for recruiting new faculty to enhance interactions, collaborations and research opportunities in the proposed thematic area(s).

- i. Strategies to incorporate this planning activity into the Cancer Center Support Grant (CCSG or P30)

#### Plans for Evaluating Progress

- a. Internal Processes
- b. External Processes

#### Human Subjects (Follow PHS Form 398 Instructions)

#### Vertebrate Animals (Follow PHS Form 398 Instructions)

#### Literature Cited (Follow PHS Form 398 Instructions)

#### Consortium/Contractual Arrangements (Follow PHS Form 398 Instructions)

#### Consultants (Follow PHS Form 398 Instructions)

#### Checklist

#### Appendix

4. Detailed Budget for Initial Budget Period: Use Form Page 4 of the Form PHS 398 application kit. This budget will be divided into three parts: an administrative component, which will include all salaries for the P.I., co-P.I. and critical administrative personnel, supplies, travel etc.; a Planning and Evaluation Component, which will include all costs for analyses, meetings, and retreats, as well as all costs for consultants and advisors; and a Developmental Component, which will include all costs for pilot projects, resource development and new recruitments to the institution. Provide the following:
  - a. Total Initial Budget, which is the sum of the budgets for the Administrative Component, the Planning and Evaluation Component and the Developmental Component
  - b. The Initial Budget for the Administrative Component.
  - c. The Initial Budget for the Planning and Evaluation Component.
  - d. The Initial Budget for the Developmental Component.
5. Budget for Entire Proposed Project Period using Form Page 5. This budget will also be presented in four sections as noted above. However, it is important that the development of budgets follows the maturation of the planning process. For example, more funds might be dedicated to retreats and workshops in the first year and more to specific pilot projects and evaluation of progress in subsequent years.
6. Letters of Commitment. The following letters of commitment should accompany the application: 1) a letter of commitment from an appropriate institutional official supporting the integration of research

at the interface of aging and cancer. If possible, this letter should include any specific allocations of space, positions or discretionary resources that the institution will commit to the development of a cancer center "Program;" 2) a letter of commitment from the Cancer Center Director. If there is an NIA Aging Research Center in the institution, this letter of commitment should be co-signed by the Cancer Center Director and the Aging Research Center Director, ensuring that during the development of this new "Program," the resources of the Cancer Center and the Aging Research Center will be made available to facilitate the development of a cancer center "Program."

7. Implementation Plan:

- a. Background of aging and cancer research activities in the Institution(s). Provide a historical perspective of how aging research and cancer research in the institution has developed within the institution in the past. If there is an Aging Research Center in the institution, describe the research thrusts of this Center and how it has related to the Cancer Center in the past. Identify and discuss specific examples, if any, of collaborations between aging and cancer scientists in your institution within the last five years. Discuss past barriers for successfully integrating aging and cancer research within the cultural, organizational, and community setting of your institution(s) (Limited to 5 pages)
- b. Potential opportunities within your institution(s). Provide a list of all of the existing faculty involved in aging research in your institution(s) and include their departmental affiliation (or equivalent); their active, peer-reviewed research support by identification number, source of support, title and total dollars; indicate those who are already members of the Cancer Center; and indicate those most likely to become members of a Cancer Center "Program." Provide a list of members of the Cancer Center who have the greatest potential to become members of a "Program," their departmental affiliation, and their active peer-reviewed research support by identification number, source or support, title and total dollars. Indicate from among the group of potential "Program" members the most probable scientific areas for collaboration and integration of cancer and aging research. (Limited to 5 pages of narrative)
- c. Specific thematic areas proposed for development. Discuss which of the seven thematic areas of the Workshop Report you intend to develop. Note that while applicants have the flexibility to work within any one of the seven areas, one of these areas must be either "Treatment Efficacy and Tolerance", "Effects of Comorbidity", and/or "The Biology of Aging and Cancer". Provide a rationale for developing each thematic area based on the existing scientific expertise in your institution(s), identify the research priorities in the center defined in the Workshop Report that you expect to address and discuss any plans to recruit additional faculty to augment and strengthen a thematic area. It is important for the applicant to focus on areas that will give the cancer center the greatest potential for developing an established "Program" (or an equivalently effective model) in the center within the 5-year period of the grant. (Limited to 5 pages of narrative for each thematic area) Note that while applicants have the flexibility to work within any one of the seven areas, one of these areas must be either "Treatment Efficacy and Tolerance", "Effects of Comorbidity", and/or "The

Biology of Aging and Cancer".

- d. Chronological overview of all projected planning, priority setting and implementation activities. It is important to establish a predicted time-line and milestones within the five-year period of this grant that clearly maps out the progression of the center toward establishing a permanent "Program"(or an equivalently effective model) in the center that integrates research at the interface of aging and cancer research. For example, the first year might be used primarily to conduct meetings and retreats that identify the best opportunities for developing competitive research and to initiate several pilot projects in which collaborations can be developed easily; the second year might be devoted to initiating new pilot projects and recruiting new scientists to the institution; the third year might be devoted to enhancing existing resources and/or establishing a specialized resource and submitting grants to funding agencies; and the fourth and fifth years might be devoted to the conduct of more pilot projects, the submission of more grant applications, consolidating new peer reviewed support and integrating the Program into the CCSG. (Limited to 3 pages)
- e. Plans for conducting meetings, workshops and retreats. Specifically propose the meetings, workshops and retreats that you expect to conduct, denote their purpose and expected results, the individuals, by name, that you believe will participate, and the project year during which this activity will take place (e.g., first year, second year, third year etc.). Some meetings may be held with the senior administrative officials of the institution, some with senior scientific leaders who will participate in the future "Program", and others with groups of scientists to identify scientific projects and link co-investigators in specific thematic areas.  
(Limited to 5 pages)
- f. Plans for developing pilot research projects in the proposed thematic areas.
  - 1. Outline the process by which collaborative pilot research projects will be solicited within the institution and the internal peer review group that will judge the merit of the proposals for funding. (NOTE: this group could be the Steering Committee {see 8a below} or a standing cancer center committee augmented to include aging research expertise). Merit judgments must include the scientific quality of the pilot project and the degree to which it successfully addresses one or more of the research priorities identified in the Workshop Report. (Limit to 2 pages)
  - 2. Provide a list of examples of collaborative pilot projects that potentially could be considered under each of thematic areas proposed in the application. Each example should be no more than a few paragraphs, but it should provide peer reviewers with enough information to judge the potential of the planning activity to generate state-of-the-art research and a stable research base that will develop into a strong cancer center "Program." (Limit to 5 pages)

3. If the center is ready to propose full pilot projects for funding, provide the following: the names of the co-principal investigators (NOTE: Each pilot research project should be limited to approximately 2 years of support, in general should not exceed \$100,000 in direct costs, and must be co-led by a cancer scientist and a scientist engaged in aging research unless one individual clearly has the expertise to bridge both cancer and aging); the biographical sketches of the co-principal investigators, the title of the research project, a one paragraph abstract of the project, the specific aims of the project and one paragraph describing how the project falls within one of the thematic areas of the application and how it addresses one or more of the research priorities identified in the Workshop Report. (Limit to 5 pages per pilot project)
  - g. Plans for enhancing currently existing CCSG resources and/or for developing specialized resources for enhancing aging and cancer research. If specialized resources are developed, describe the resource and explain how it will enhance research at the aging-cancer interface, and facilitate the peer reviewed research capabilities of the Center "Program." The resource can be a new resource or it can be an activity that enhances an existing cancer center shared resource. Explain how existing cancer center shared resources cannot satisfy this need(s) adequately. Provide a list, and brief description, of existing shared resources. (Limit to 2 pages per resource)
  - h. Plans for recruiting new faculty to enhance interactions, collaborations and research opportunities in one or more of the proposed thematic areas of research. It is not required that every applicant have specific plans for recruiting new faculty. However, if certain scientists have already been identified who will enhance collaborative research, provide a description of the kind of individual(s) who will be recruited, how his/her research will enhance the research objectives of the "Program," and when a recruitment(s) will be implemented (e.g., first year, second year, etc.)
  - i. Strategies for incorporating this planning activity into the NCI Cancer Center Support Grant (CCSG or P30). A clear plan for including the salaries of the co-program leaders, specialized resources and developmental funds for pilot projects should be provided that takes into account the next competing renewal application for the CCSG. (NOTE: the recipient will not lose any of the funds from this planning grant if certain budget items are incorporated into the CCSG; the P20 budget will be made available for other purposes consistent with accomplishing the objective of establishing a stable cancer center "Program.")
8. Plans and Processes for Evaluating Progress
  - a. Internal Processes. This planning activity is required to have a Steering Committee (SC) co-chaired by principal and co-principal investigators. The SC must include in its membership the cancer center director, the Aging Research Center director (if any), senior

investigators who are members of the cancer center, and senior investigators in aging research. The SC will be charged with making recommendations for the nature and purpose of all planning activities (e.g., retreats, workshops), the methods for seeking collaborative projects, optionally reviewing pilot projects for scientific and programmatic merit, making recommendations for dispensing the budget for initiating pilot projects, and developing resources, assessing progress, recommending mid-course corrections and making recommendations for responding to the advice of the external advisory committee of the Cancer Center.

- b. External Processes. The development of the "Program" in the cancer center should receive annual review for progress by the standing external advisory committee of the NCI Cancer Center. The external advisory committee should provide its evaluations and recommendations in writing. This document should be submitted as part of the annual non-competing renewal application of this P20 grant, not the CCSG.
- 9. Human Subjects (Follow PHS Form 398 Instructions)
- 10. Vertebrate Animals (Follow PHS Form 398 Instructions)
- 11. Literature Cited (Follow PHS Form 398 Instructions)
- 12. Consortium Contractual Arrangements (if any) (Follow PHS Form 398 Instructions)
- 13. Consultants (Follow PHS Form 398 Instructions)
- 14. Checklist (Follow PHS Form 398 Instructions)
- 15. Appendix (Follow PHS Form 398 Instructions)

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application WITHOUT appendices, including the Checklist, and three signed, photocopies, in one package to:

Center for Scientific Review  
National Institutes Of Health  
6701 Rockledge Drive, Room 1040, MSC 7710  
Bethesda, MD 20892-7710



Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application WITH appendices must be sent to:

Referral Officer  
Division of Extramural Activities  
National Cancer Institute  
6116 Executive Boulevard, Room 8041, MSC-8329  
Rockville, MD 20852 (express courier)  
Bethesda, MD 20892-8329

APPLICATION PROCESSING: Applications must be **received** (not postmarked) by January 14, 2003. If an application is received after that date, it will be returned to the applicant without review.

#### PEER REVIEW PROCESS:

Upon receipt, applications will be reviewed for completeness by the Center for Scientific Review and responsiveness to the ELIGIBILITY REQUIREMENTS and the SPECIAL REQUIREMENTS of this RFA by the NCI. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities of the NCI. All applications will be evaluated in accordance with the REVIEW CRITERIA stated below. As part of the initial merit review, all applications will be evaluated in accordance with the review criteria stated below and receive a written critique. Those that receive a priority score will undergo a second level review by the National Cancer Advisory Board (NCAB).

#### REVIEW CRITERIA:

Because of the special nature of this planning grant RFA, the review criteria are not organized under the traditional headings of Significance, Approach, Environment, Investigator, and Innovation typically used for NIH research Grants. Reviewers will be instructed that this is a planning and development activity and they are to use the criteria indicated below and not the typical criteria used for research grants:

- The extent to which the Principal Investigator (and the co-Principal Investigator, if identified) can attain a high standard as a successful senior scientist(s) in integrating cancer and aging research, provide both scientific and administrative leadership to this planning and development activity, and ultimately serve as a Program Director of a "Program" in the Cancer Center dedicated to integrating aging and cancer research.
- The extent of confidence conveyed by the letters of commitment that the institution is committed to this effort and that the NCI Cancer Center Director (and the NIA Aging Research Director, if

present) will encourage and facilitate the development of this "Program." This includes allocations of any additional space, faculty recruitments or discretionary resources needed to develop a high quality collaborative research effort.

- Adequacy of the qualifications of the members of the Steering Committee to oversee this planning effort, providing oversight and recommendations to ensure that the effort remains on track toward a successful formation of an NCI Cancer Center "Program" with a stable, peer-reviewed, funded research base.
- The extent of confidence that the methods proposed for integrating scientists and other participants in aging and cancer research will successfully overcome any past or potential barriers within the cultural, organizational and community setting of the institution.
- The quality and scientific capabilities of the faculty identified within the institution to develop an interactive, integrated group of researchers who have the potential to conduct high quality research that bridges the aging and cancer research interface.
- The feasibility within the 5-year timeframe of this total planning effort of successfully addressing those thematic research areas (as indicated by the "Workshop Report") selected for development.
- The quality and significance of the example pilot projects for collaborative research selected to address the high priority areas of research as indicated in the "Workshop Report" in each proposed thematic area. If full pilot projects are proposed in the first year, the merit and significance of these projects.
- Adequacy and rationale for exploring the development of any proposed specialized core resources that will facilitate and enhance research at the interface of aging and cancer and not duplicate existing shared resources supported by the CCSG.
- The adequacy of the process proposed for soliciting collaborative pilot projects within the institution that bridges aging and cancer research and the adequacy of the process for evaluating pilot projects to ensure that those funded are high quality research.
- Adequacy of the plan for integrating this planning effort as a "Program" within the Cancer Center Support Grant of the NCI-designated Cancer Center.
- Adequacy of the administrative support for carrying out the everyday needs of this developmental effort.
- Adequacy of, and rationale for, the budget distribution in earlier versus later years of this effort to facilitate interactions and develop a collaborative, funded research base that bridges cancer and aging research.

## Overall Priority Score:

The overall priority score should take into account how well all of the factors above are likely to result in a stable, peer-reviewed, funded research base of a cancer center "Program" that fosters continuing scientific interactions and collaborations at the interface of aging and cancer research.

**ADDITIONAL REVIEW CRITERIA:** In addition to the above criteria, your application will also be reviewed with respect to the following:

- o **PROTECTIONS:** The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.
- o **INCLUSION:** The adequacy of plans to include subjects from both genders and all racial and ethnic groups (and subgroups) as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)
- o **BUDGET:** The reasonableness of the proposed budget and the requested period of support in relation to the proposed planning and development activity.

## RECEIPT AND REVIEW SCHEDULE

|                                  |                      |
|----------------------------------|----------------------|
| Letter of Intent Receipt Date:   | December 17, 2002    |
| Application Receipt Date:        | January 14, 2003     |
| Peer Review Date:                | June 2003            |
| Council Review:                  | September 8-10, 2003 |
| Earliest Anticipated Start Date: | September 30, 2003   |

**AWARD CRITERIA**

Criteria that will be used to make award decisions include:

- Scientific merit as determined by peer review
- Availability of funds
- Programmatic Priorities

## REQUIRED FEDERAL CITATIONS

### MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: *(if applicable)*

Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH

Guide for Grants and Contracts, June 12, 1998:  
<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

**INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH:** (*if applicable*) It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines are available at

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

**REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS:** NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

**HUMAN EMBRYONIC STEM CELLS (HESC):** Criteria for federal funding of research on hESCs can be found at [http://grants.nih.gov/grants/stem\\_cells.htm](http://grants.nih.gov/grants/stem_cells.htm) and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov>). It is the responsibility of the applicant to provide the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

**PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:** The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access

to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm).

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

**URLs IN NIH GRANT APPLICATIONS OR APPENDICES:** All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

**HEALTHY PEOPLE 2010:** The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople/>.

**AUTHORITY AND REGULATIONS:** This program is described in the Catalog of Federal Domestic Assistance No. 93.866 and No. 93.397, and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

## **NOTICE OF LIMITED COMPETITION INTEGRATING CANCER AND AGING RESEARCH IN NCI-DESIGNATED CANCER CENTERS**

Release Date: September 20, 2002

NOTICE: NOT-CA-02-027

National Cancer Institute (NCI)

(<http://www3.cancer.gov/orientation/>)

National Institute on Aging (NIA)

(<http://www.nia.nih.gov/>)

The National Institute on Aging and the National Cancer Institute announces a limited competition for Planning Grants (P20s) for developing aging/cancer "Programs" (or equivalently effective models) that will become incorporated as stable components of Cancer Center Support Grants (CCSGs). This planning activity will be dedicated to fostering interactions and collaborations between basic, clinical and population scientists at the interface of cancer and aging research, creating a stable, peer-reviewed funded research base at this interface which meets the requirements of a "Program" by NCI CCSG Guidelines, and incorporating this "Program" into the CCSG as a stable inter-disciplinary activity of the Cancer Center. This planning and development effort will be regularly evaluated for progress by the standing "External Advisory Group" of the Cancer Center and will make heavy use of existing resources and infrastructure supported by the CCSG.

NCI will contact all grantees holding CCSGs regarding the application procedures and format.

### **INQUIRIES**

Inquiries are encouraged, and the opportunity to clarify issues and answer questions is welcome. Inquiries may be directed to:

Patricia McCormick, Ph.D.  
Program Director  
Cancer Centers Branch  
National Cancer Institute  
Telephone: (301) 496-8531  
FAX: (301) 402-0181  
Email: pm60y@nih.gov

Or

Rosemary Yancik, Ph.D.  
Program Director  
Geriatrics Branch, Geriatrics and Clinical Gerontology Program  
National Institute on Aging  
Telephone: (301) 496-5278  
FAX: (301) 402-1784  
Email: yancikr@nia.nih.gov



Office of Centers,  
Training, and  
Resources

Cancer Centers Branch

6116 Executive Boulevard  
Suite 700, MSC 8345  
Bethesda, Maryland 20892-8345  
Tel: (301) 496-8531  
Fax: (301) 402-0181  
<http://www.nci.nih.gov/cancercenters/>

U.S. Department of Health  
and Human Services  
National Institutes of Health

November 19, 2002

**TO:** Directors, NCI Cancer Centers

**FROM:** Chief, Cancer Centers Branch, OCTR, NCI  
Program Director, Geriatrics Branch, Geriatrics and Clinical Gerontology, NIA

**SUBJECT:** Clarification of Purpose and Objectives of the RFA CA-03-504 for Planning and Development (P20) Grants Integrating Aging and Cancer Research in NCI-designated Cancer Centers

Attached is a statement of clarification of the purpose and objectives of the RFA CA-03-504 for Planning and Development (P20) Grants Integrating Aging and Cancer Research in NCI Cancer Centers. Please distribute this document to any investigators who are planning to respond to this RFA.

Thank you for your attention to our request.

**RFA CA-03-504 for Planning and Development (P20) Grants  
Integrating Aging and Cancer Research in NCI-Designated Cancer Centers**

**Clarification of Purpose and Objectives**

The goal of this research solicitation is to expand the capacity of Cancer Centers to engage in pioneering research that concentrates on aging- and age-related aspects of human cancer. The research guidance for this solicitation comes from the NIA/NCI co-sponsored workshop, “Exploring the role of Cancer Centers for Integrating Aging and Cancer Research” June, 2001. The emphasis for the workshop, in the discussions, and for this research solicitation is on projects that are clearly relevant to human cancer and aging. Under the RFA Research Scope, any of the seven thematic areas identified in the Workshop Report may be pursued in forming the research base of the proposed program, but it is stipulated that the application must include one or more of these areas:

- o Treatment Efficacy and Tolerance
- o Effects of Comorbidity
- o The Biology of Aging and Cancer

As applicants are conceptualizing their proposed research programs, we have received several questions regarding the extent to which a focus on basic research themes (associated primarily with The Biology of Aging and Cancer and the use of animal models) would be compatible with the intent of this solicitation on human cancer.

It should be understood that the intent of this solicitation is to develop a “Program” whose research projects have a clear relevance to human cancer and aging. This “clarification” regarding the focus of this RFA is not intended to exclude the development of a research program that incorporates a basic research theme or projects. Rather, it is intended to make clear that the primary goal is to develop research continuum that will foster and sustain the development of a knowledge base clearly relevant to human cancer and aging. Thus, basic science projects, including those reliant on mouse or other non-human models, must indicate how the research initiatives are pertinent to cancer in the elderly and will translate into human applications. All basic research should be linked to human cancer and/or to hypotheses proposed for testing in humans. This can be accomplished in an NCI clinical or comprehensive cancer center by establishing a “Program” that is highly interdisciplinary and includes the basic, clinical, behavioral and population sciences or by linking a very basic “Program” strategically to the more applied programs in the cancer center. A basic cancer center must seek collaborations with more applied organizations such as NCI clinical or comprehensive cancer centers or industry to orient their programs to human applications. As is always the case, NCI cancer centers are expected to enlist the resources and expertise of the entire institution in the development of a Program, which can also include the use of existing shared resources or the establishment of new shared resources that would enhance the development of a Program.